## REMARKS

Claims 16 and 22 have been cancelled.

Claims 13, 21, and 25 have been amended to remove the recitation "or prophylaxis" and to provide better antecedent agreement.

Claim 13 has also been amended to remove the phrase "excluding the pathologies affecting the optic nerve" and now positively recites "wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, retina, vitreous body, and choroidea." Support for this amendment is found in the specification at, for example, page 7, lines 24-25, page 18, lines 1-5, and in original claims 3 and 10. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

Claim 21 has also been amended to remove the phrase "excluding retinal pathologies and pathologies affecting the optic nerve" and now positively recites "wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, vitreous body, and choroidea." Support for this amendment is found in the specification at, for example, page 7, lines 24-25, page 18, lines 1-5, and in original claims 3 and 10. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

**Enablement Rejection**

Claims 13, 14-20, 21, 22-24, 25, and 26-36 were rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. (Paper No. 03312005 at 2). In making

the rejection, the Examiner asserted that "the specification ... does not reasonably provide enablement for a method of preventing pathology affecting the internal eye." (*Id.* at 2-3).

The Examiner acknowledged, however, that the specification is "enabling for treating pathology affecting the internal eye." (*Id.* at 2).

With a view toward furthering prosecution, claims 13, 21, and 25 have been amended to remove the recitation "or prophylaxis" from which claims 14-15 and 17-20, 23-24, and 26-36 depend, respectively. Accordingly, it is respectfully submitted that the rejection is rendered moot and should be withdrawn.

**Written Description Rejections**

Claims 13, 14-20, 21, and 22-24 were rejected under 35 USC §112, first paragraph for lack of written description. (Paper No. 03312005 at 5). In making the rejection, the Examiner asserted that "[c]laim 13 is drawn to a method for treating a pathology affecting the internal tissues of the eye 'excluding the pathologies affecting the optic nerve.'" (*Id.* at 5-6). The Examiner further asserted that "[l]ike the instant [c]laim 13, [c]laim 21 proposes a method for the treatment of the eye 'excluding' a mechanistic pathway," and "[c]laim 21 is drawn to a method for treating a pathology affecting the internal tissues of the eye 'excluding retinal pathologies and pathologies affecting the optic nerve.'" (*Id.* at 6). The Examiner then asserted that "[t]here is no support for the phrase 'excluding the pathologies affecting the optic nerve' or 'excluding retinal pathologies and pathologies affecting the optic nerve' in the instant specification," and "there is no mention of a method of treating the eye 'excluding' a mechanistic pathway in the instant specification." (*Id.*).

The Examiner then concluded that "the disclosure of the instant specification is not sufficient to support the concept of 'excluding the pathologies affecting the optic nerve' or 'excluding retinal pathologies and pathologies affecting the optic nerve,'" and "[o]n this basis, the examiner is construing instant [c]laims 13 and 21 as including any method of treating a pathology affecting the internal tissues of an eye comprising administering nerve growth factor to a subject." (*Id.*).

As is well accepted, there is a ***strong presumption*** that an adequate written description of the claimed invention is present in an application as filed. *See In re Werthheim*, 191 USPQ 90, 97 (CCPA 1976); and MPEP §2163(II)(A). Further, an applicant may show possession of the claimed invention by describing it using descriptive means such as, for example, words, structures, figures, diagrams and formulas. *See* MPEP §2163(I).

We note that both phrases are fully supported in the specification as filed and in the original claims. There is virtually *in haec verba* support for these phrases in the specification at, for example, page 14, lines 5-11 ("except retina and optic nerve pathologies") and in original claim 9 ("except retinal pathologies and pathologies affecting the optic nerve"). *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (I). *See also* MPEP 2173.05(i) "Negative Limitations" ("The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation." "Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims.").

With a view toward furthering prosecution, claim 13, however, has been amended to remove the phrase "excluding the pathologies affecting the optic nerve" and now positively recites "wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, retina, vitreous body, and choroidea." Claim 21 has also been amended to remove the phrase "excluding retinal pathologies and pathologies affecting the optic nerve" and now positively recites "wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, vitreous body, and choroidea."

Accordingly, it is respectfully submitted that the rejection is rendered moot and should be withdrawn.

Claims 13, 14-20, 21, and 22-24 were ***again*** rejected under 35 USC §112, first paragraph for lack of written description. (Paper No. 03312005 at 6). In making the rejection, the Examiner asserted that "[c]laims 13-20 are drawn to a method for the treatment or prophylaxis of a pathology affecting the internal tissues of an eye, excluding the pathologies affecting the optic nerve, comprising the administration of a nerve growth factor to a subject" and "[c]laims 21-24 are drawn to a method for the treatment or prophylaxis of a pathology affecting the internal tissues of an eye, excluding retinal pathologies and pathologies affecting the optic nerve, comprising the administration of a nerve growth factor to a subject." (*Id.* at 6-7). The Examiner further asserted "[t]he language 'excluding the pathologies affecting the optic nerve' and 'excluding retinal pathologies and pathologies affecting the optic nerve' is ***not specifically enumerated*** in the instant specification." (*Id.*). (Emphasis added). The Examiner then concluded that "the disclosure of the instant specification is not sufficient

to support the concept of 'excluding the pathologies affecting the optic nerve' and 'excluding retinal pathologies and pathologies affecting the optic nerve.'" (*Id.*).

We note that this appears to be the ***same*** written description rejection traversed above. Therefore, the arguments made above apply with equal force to the current rejection.

As stated above, both phrases are fully supported in the specification as filed and in the original claims. There is virtually *in haec verba* support for these phrases in the specification at, for example, page 14, lines 5-11 ("except retina and optic nerve pathologies") and in original claim 9 ("except retinal pathologies and pathologies affecting the optic nerve").

With a view toward furthering prosecution, claim 13, however, has been amended to remove the phrase "excluding the pathologies affecting the optic nerve" and now positively recites "wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, retina, vitreous body, and choroidea." Claim 21 has also been amended to remove the phrase "excluding retinal pathologies and pathologies affecting the optic nerve" and now positively recites "wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, vitreous body, and choroidea."

Accordingly, it is respectfully submitted that the rejection is rendered moot and should be withdrawn.

**Anticipation Rejections**

Claims 13-36 were rejected under 35 USC §102(b) as anticipated by Lambiase, WO 98/48002, ("Lambiase '002"). (Paper No. 03312005 at 8-9).

Lambiase '002 discloses that "nerve growth factor (NGF) is used for the storage of corneas in culture, for the production and the storage *in vitro* of single cell populations of the corneal morphological and functional unit (*i.e.*, epithelium, stroma/keratocytes and endothelium) and of the conjunctival epithelium, and for the production and the storage of corneal and conjunctival tissues, in particular for transplantation purposes." (Abstract). "The NGF is also proposed for use in the therapy and/or the prophylaxis of diseases of the corneal surface, wherein a lack of integrity of the corneal and conjunctival morphological and functional unit occurs, in particular for pathologies having a dystrophic or neurodystrophic basis, both congenital and acquired." (*Id.*). .

In making the rejection, the Examiner asserted that Lambiase "'002 discloses methods of treating pathologies affecting the internal tissues of the eye by administering between 10 to 500 μg/ml of nerve growth factor to an individual (abstract and page 12, lines 14). The NGF can be administered either topically or over the ocular surface of an individual and treats corneal and/or conjunctival affects (page 12, line 31 - page 13, line 23)." (*Id.* at 8). The Examiner further asserted that "[i]n another embodiment, the NGF may be administered - by introduction into the anterior chamber of the eye (page 12, lines 17-20). Like the instant application, the NGF may be in the form of an ophthalmic solution or gel and may be administered via a bandage or medical contact lens (page 12, lines 10-13). The NGF medicament can be of human origin and can be used to treat disorders originating from laser treatment (Claim 9, 15)." (*Id.*).

The Examiner then asserted that "[i]t is the examiner's position that, inherently, the composition advanced by [Lambiase] '002, when injected into the eye, treats the same eye-related disorders as the instant application. Since the essential elements of the [Lambiase] '002 composition and method are identical to the instant compositions and methods (that is, injecting a composition comprising 10 to 500 μg/ml of nerve growth factor to an individual), the composition would inherently treat the same disorders as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by [Lambiase] '002 anticipates the compositions enumerated in the instant claim set." (*Id.* at 8-9).

For the reasons set forth below, the rejection respectfully is traversed.

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir 1984).

Furthermore, in a §102(b) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). "Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990). The Examiner is required to point to the

disclosure in the reference "***by page and line***" upon which the claim allegedly reads. *Chiong v. Roland*, 17 USPQ2d 1541, 1543 (BPAI 1990).

Initially, we note claim 13 has been amended to remove the phrase "excluding the pathologies affecting the optic nerve" and now positively recites "wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, retina, vitreous body, and choroidea." Claim 21 has also been amended to remove the phrase "excluding retinal pathologies and pathologies affecting the optic nerve" and now positively recites "wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, vitreous body, and choroidea."

We also note that the Examiner has failed to acknowledge or address the limitation "wherein said nerve growth factor passes through the external tissues of said eye to said internal tissues" in claims 13, 21, and 25 (from which claims 14-15 and 17-20, 23-24, and 26-36 depend, respectively). The Examiner also failed to acknowledge or address the range limitation of 200 to 500 μg/ml in claim 25 (and dependent claims 26-36).

Having failed to address these limitations, the Examiner failed to identify where in Lambiase '002 each and every element of claims 13, 21, and 25 are shown. That, however, was the Examiner's burden. Accordingly, the rejection is insufficient as a matter of law and fact to support a conclusion of anticipation, and for this reason alone, the rejection should be withdrawn with respect to claim 13 (and dependent claims 14-15 and 17-20) and claim 21 (and dependent claims 23-24), and claim 25 (and dependent claims 26-36).

The Examiner relied on Lambiase '002 for "disclose[ing] methods of treating pathologies affecting the internal tissues of the eye by administering between 10 to 500 μg/ml of nerve growth factor to an individual." (Paper No. 03312005 at 8). The Examiner then took the position that "inherently, the composition advanced by [Lambiase] '002, when injected into the eye, treats the same eye-related disorders as the instant application" and concluded that "the composition advanced by [Lambiase] '002 anticipates the compositions enumerated in the instant claim set." (*Id.* at 8-9).

The Examiner appears to have failed to appreciate that the applicant is claiming a method of treatment, not a composition *per se*. Thus, even if the Examiner's characterization of Lambiase '002 is accepted as correct (which it is not), the Examiner has not demonstrated that Lambiase '002 discloses what is claimed. Nor has the Examiner identified any evidence that would suggest Lambiase '002 discloses the method of treatment currently claimed. Accordingly, the rejection is insufficient as a matter of fact and should be withdrawn.

Furthermore, it is respectfully submitted that the Examiner has misinterpreted the disclosure of Lambiase '002. Lambiase '002 is discussed at page 6, lines 1-7 and page 7, lines 27-30 of applicant's specification. Lambiase '002 discloses treating pathologies affecting the ***surface*** of the eye (*i.e.*, cornea and conjunctiva) by administration of the "composition" on the eye surface and treating pathologies of the internal tissues of the eye by administration of the "composition" into the eyeball by injection ("administration in the anterior chamber of the eye"). *See* Lambiase '002 at page 11, line 27 to page 12, line 30. Lambiase '002 is concerned with administration of the "composition" *in situ*. In other words, right in the ocular tissues affected by the

disorder to be treated. If the disorder to be treated concerns the cornea or the conjunctiva, the administration would be "extraocular," *i.e.* between the eyeball and the eyelid. If the disorder to be treated affects the internal tissues (endothelial pathologies, as recited in the disclosure), the administration is carried out by injection in the anterior chamber of the eye.

To the contrary, applicant's claimed method is concerned with the administration of the composition (*e.g.*, in the form of eye-drops) "over an ocular surface," which composition is able to pass through the ocular tissues and reach the internal tissues, so that it does not need at all to be injected *in situ*, not even to treat pathologies affecting the internal tissues of the eye. *See* specification, at page 6, line 18 to page 9, line 5. It is clear that Lambiase '002 only concerns applying the product to the damaged site as opposed to the claimed invention, which is entirely based on the unexpected finding that NGF is able to ***pass through the ocular tissues***, so that, in order to treat internal ocular tissues, the product need only be applied onto the ocular surface, *i.e.*, it does not need to be directly applied onto the affected site (wound). Accordingly, for this additional reason, the rejection should be withdrawn.

We further note that the Examiner asserted "*inherently*, the composition advanced by [Lambiase] '002, when injected into the eye, treats the same eye-related disorders as the instant application." An examiner must provide rationale or evidence tending to show inherency, not mere speculation. *See* MPEP § 2112 (8th Ed., Rev. 3, Aug. 2005, at p. 2100-57) ("The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir.

1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)."). This, the Examiner has not done. For this additional reason, the rejection should be withdrawn.

The rejection is also devoid of any discussion of claims 14-15, 17-21, and 23-36, separate from claim 13. Accordingly, the record is devoid of any evidence that the Examiner individually considered claims 14-15, 17-21, and 23-36. It is axiomatic, however, that each claim is to be examined on its own merits. It is also axiomatic that a dependent claim is not *per se* anticipated by prior art that anticipates the base claim. Accordingly, "[e]xaminers are reminded that a dependent claim is directed to a combination including everything recited in the base claim and what is recited in the dependent claim. ***It is this combination that must be compared with the prior art, exactly as if it were presented as one independent claim.***" MPEP § 608.01(n) (8th ed. Rev. 2, May 2004, pp. 600-80). This the Examiner has not done. Accordingly, the rejection is both factually and legally deficient as to claims 14-15, 17-21, and 23-36. For this additional reason, the rejection should be withdrawn as to claims 14-15, 17-21, and 23-36.

Claims 13-16, 18-19, 21-22, 24-28, and 30-36 were rejected under 35 USC §102(b) as anticipated by Finkenaur *et al.*, EPA 0312208A1 ("Finkenaur"). (Paper No. 03312005 at 9).

For the reasons set forth below, the rejection, respectfully is traversed.

Finkenaur discloses that "[g]el formulations containing polypeptide growth factors having human mitogenic or angiogenic activity are provided. The gel

formulations are useful for topical or incisional ***wound*** healing for cutaneous wounds, in the anterior chamber of the eye and other ophthalmic wound healing." (Abstract.)

In making the rejection, the Examiner asserted that Finkenaur "disclose aqueous gel formulations comprising 1 to 500 μg/ml of a polypeptide growth factor, such as nerve growth factor (abstract and page 3, lines 25- 48). Said nerve growth factor can be used for wound healing in the anterior chamber of the eye (abstract). Said wound healing composition can be delivered to an individual via a bandage (page 2, lines 49-50)." (Paper No. 03312005 at 9).

The Examiner then asserted that "[i]t is the examiner's position that, inherently, the composition advanced by [Finkenaur], when injected into the eye, treats the same eye-related disorders as [t]he instant application. Since the essential elements of the '208 composition and method are identical to the instant compositions and methods (that is, injecting a composition comprising 1 to 500 μg/ml of nerve growth factor to an individual), the composition would inherently treat the same disorders as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by [Finkenaur] anticipates the compositions enumerated in the instant claim set." (*Id.*).

Initially, we note that Finkenaur was considered and applied in the first Office Action (Paper No. 6 at p. 3) in a 35 U.S.C. § 102(b) rejection by the previous Examiner. After reviewing our Response filed March 27, 2003, the previous Examiner withdrew the rejection in its entirety. The Examiner conceded that Finkenaur fails to "**teach [a] formulation administered [to] the ocular surface of the eye**." (*See* Paper No. 9 at 4-5) (emphasis added). Finkenaur was *again* considered and applied in a 35

U.S.C. § 103(a) rejection by the previous Examiner in a Final Office Action mailed May 20, 2003. (*Id.*). And again, after reviewing our Response filed November 20, 2003, the previous Examiner withdrew the rejection in its entirety. (*See* Paper No. 20031223 at 8). In other words, the disclosure of Finkenaur has already been considered and applied by the PTO ***twice***. In view of the arguments made, the PTO ***conceded twice*** that Finkenaur does not disclose the method claimed and is not a bar to patentability under either §102 or §103. For this reason alone, the current rejection, being based on the same disclosure, should be withdrawn.

In view of the foregoing, we respectfully remind the Examiner that "[p]iecemeal examination should be avoided as much as possible. ***The examiner ordinarily should reject each claim on all valid grounds available.***" MPEP § 707.07(g), 8th ed., Rev. 1, February 2003, p. 700-116.).

As discussed above, anticipation requires "identity of invention." *Glaverbel Societe Anonyme,* 33 USPQ2d at 1498. Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *Marshall*, 198 USPQ at 346. In a §102(b) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. *Kalm*, 154 USPQ at 12; *Scripps*, 18 USPQ2d at 1010.

In the interest of saving time, we incorporate by reference our previous arguments with respect to Finkenaur as if recited in full herein. Just as before, these arguments alone are sufficient to overcome the rejection.

In addition, we note that claim 13 has been amended to remove the phrase "excluding the pathologies affecting the optic nerve" and now positively recites

"wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, retina, vitreous body, and choroidea." Claim 21 has also been amended to remove the phrase "excluding retinal pathologies and pathologies affecting the optic nerve" and now positively recites "wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, vitreous body, and choroidea."

We also note that the Examiner has failed to acknowledge or address the limitation "wherein said nerve growth factor passes through the external tissues of said eye to said internal tissues" in claims 13, 21, and 25 (from which claims 14-15 and 17-20, 23-24, and 26-36 depend, respectively). The Examiner also failed to acknowledge or address the range limitation of 200 to 500 μg/ml in claim 25 (and dependent claims 26-36).

Having failed to address these limitations, the Examiner failed to identify where in Finkenaur each and every element of claims 13, 21, and 25 are shown. That, however, was the Examiner's burden. Accordingly, the rejection is insufficient as a matter of law and fact to support a conclusion of anticipation, and for this reason alone, the rejection should be withdrawn with respect to claim 13 (and dependent claims 14-15 and 17-20) and claim 21 (and dependent claims 23-24), and claim 25 (and dependent claims 26-36).

Furthermore, it is respectfully submitted that the Examiner has misinterpreted the disclosure of Finkenaur. Finkenaur is discussed at p. 5 of applicant's specification. The specification states:

> With specific reference to the disorders affecting ***the exposed ocular surface***, i.e. corneal and conjunctival diseases, EP-A-0312208 discloses gel formulations for use in the treatment of epithelial lesions and epithelial pathologies in general, including lesions and pathologies of the ocular surface. The said formulations contain an active ingredient which may be indiscriminately chosen among the various molecules whose name contains the expression "growth factor". Although ***the description is exclusively concerned with the epidermal growth factor (EGF)*** as the preferred active ingredient, and although activity data (*in vitro*) and formulation examples are given only for EGF, other growth factors are mentioned as well, such as FGF (fibroblast growth factor), PDGF (platelet-derived growth factor), TGF-α (transforming growth factor) or the NGF itself. The said growth factors are apparently presented as a family of molecules having equivalent characteristics and biological activity as EGF. As a matter of fact, at the current state of the knowledge, ***it is undisputed that the said growth factors have different specific targets and that they often have conflicting effects, so that they are not considered as biologically equivalent to each other.*** (emphasis added).

The various growth factors mentioned above are different individual molecules, with a different amino acid sequence, structure and molecular weight, and, above all, different receptor sites and different biological activity. For instance, EGF is a 53 amino acid polypeptide having a molecular weight of about 6000 dalton, while NGF is a 140 kdalton molecular complex. The present claims recite a method based on NGF. Finkenaur only incidentally mentioned NGF and does *NOT* disclose the method currently claimed.

Finkenaur teaches the use of EGF for the treatment of incisional wounds, based on the disclosed mitogenic properties of this compound. (See p. 2, lines 17-24). Finkenaur discloses the direct application of the product on a wound, whether it be a

surface wound or an internal wound. (See p. 4, lines 7-32). It is clear that Finkenaur concerns applying the product to the damaged site/wound as opposed to the claimed invention, which is entirely based on the unexpected finding that NGF is able to ***pass through the ocular tissues***, so that, in order to treat internal ocular tissues, the product need only be applied onto "the ocular surface," *i.e.*, it is not directly applied onto the affected site (wound).

The Examiner asserted that Finkenaur discloses that "nerve growth factor can be used for wound healing in the anterior chamber of the eye (abstract)" and "[s]aid wound healing composition can be delivered to an individual via a bandage [placed on the wound] (page 2, lines 49-50)." (Paper No. 03312005 at 9). The method claimed, however, recites that the treatment occurs by administering "over an ocular surface." As discussed above, Finkenaur discloses direct application of the composition on the wound. For example, Finkenaur discloses "soak[ing] a bandage [with a formulation to be] ***placed on the wound***." (Page 2, line 50). Thus, the rejection does not – and cannot – identify where in Finkenaur it is disclosed to administer "over an ocular surface" and "wherein said nerve growth factor passes through the external tissues of said eye to said internal tissues." Indeed, the PTO has conceded that Finkenaur fails to "**teach [a] formulation administered [to] the ocular surface of the eye**." (*See* Paper No. 9 at 4-5) (emphasis added). Because Finkenaur does not disclose each and every element arranged as recited in the claimed method, it does not anticipate any pending claims. Thus, the rejection is factually and legally deficient and should be withdrawn.

We further note that the Examiner asserted "*inherently*, the composition advanced by [Finkenaur], when injected into the eye, treats the same eye-related

disorders as [t]he instant application." An examiner must provide rationale or evidence tending to show inherency, not mere speculation. *See* MPEP § 2112 (8th Ed., Rev. 3, Aug. 2005, at p. 2100-57) ("The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)."). This, the Examiner has not done. For this additional reason, the rejection should be withdrawn.

The rejection is also devoid of any discussion of claims 14-15, 17-21, and 23-36, separate from implicitly discussing claim 13. Accordingly, the record is devoid of any evidence that the Examiner individually considered claims 14-15, 17-21, and 23-36. It is axiomatic, however, that each claim is to be examined on its own merits. It is also axiomatic that a dependent claim is not *per se* anticipated by prior art that anticipates the base claim. Accordingly, "[e]xaminers are reminded that a dependent claim is directed to a combination including everything recited in the base claim and what is recited in the dependent claim. ***It is this combination that must be compared with the prior art, exactly as if it were presented as one independent claim.***" MPEP § 608.01(n) (8th ed. Rev. 2, May 2004, pp. 600-80). This the Examiner has not done. Accordingly, the rejection is both factually and legally deficient as to claims 14-15, 17-21, and 23-36. For this additional reason, the rejection should be withdrawn as to claims 14-15, 17-21, and 23-36.

## CONCLUSION

In view of the foregoing, favorable action on the merits, including entry of the amendments, withdrawal of the rejections, and allowance of all the claims, are respectfully requested. If the Examiner has any questions regarding this paper, please contact one of the undersigned attorneys.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on March 8, 2006.

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